

Regulation 61-31

Health Care Cooperative Agreements

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2600 Bull Street | Columbia, SC 29201

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CHAPTER 1 PURPOSE, DEFINITIONS, APPLICABILITY

SECTION 101. Purpose:

These Regulations implement the legislative intent that there be a state regulatory program to permit and encourage cooperative agreements between hospitals, health care purchasers, or other health care providers which would otherwise violate federal or state anti-trust laws when the benefits outweigh disadvantages caused by their potential adverse effects on competition.

This is encouraged because the cost of improved technology and scientific methods contribute significantly to the increasing cost of health care; and cooperative agreements among hospitals, health care purchaser, and other health care providers will foster improvements in the quality of health care for South Carolinians.

SECTION 102. Definitions:

As used in this regulation:

1) “Affected persons” means a health care provider or purchaser:

a) who provides or purchases the same or similar health care services in the geographic area served or to be served by the applicants for a Certificate of Public Advantage: or

b) who has notified the Department of his interest in applications for Certificates of Public Advantage and has a direct economic interest in the decision. Other than health insurers licensed in South Carolina, persons from other states who would otherwise be considered ‘affected persons’ are not included unless that state provides for similar involvement of persons from South Carolina in a similar process in that state.

2) “Certificate of Public Advantage” mean the formal approval, including any conditions or modifications, by the Department of a contract, business or financial arrangement, or other activities or practices between two or more health providers, health provider networks, or health care purchasers that might be construed to be violations of state of federal laws.

3) “Cooperative agreement” means an agreement between two health care providers, health provider networks, or health care purchasers or among more than two health care providers, health provider networks, or health care purchasers for the sharing, allocation, or referral of patients or the sharing or allocation of personnel, instructional programs, support services and facilities, medical, diagnostic or laboratory facilities, procedures, equipment, or other health care services traditionally offered by health care facilities or other health care providers or the acquisition or merger of assets among or by two or more health providers, health provider networks or health care purchasers, provided the agreement does not involve price-fixing or predatory pricing or illegal tying arrangements.

4) “Department” means the Department of Health and Environmental Control.

5) “Health care provider” means a health care professional licensed, certified, or registered under the laws of this State, an organization licensed pursuant to Section 44-69-30 or Section 44-71-30, or a facility licensed pursuant to Section 44-7-260 or Section 44-89-40 to provide health care services or any other person as defined in Section 44-7-130(15) who provides health services in a freestanding or mobile facility.

6) “Health care purchaser” means a person or organization that purchases health care services on behalf of an identified group of persons, regardless of whether the cost of coverage of services is paid for by the purchaser or by the person receiving coverage or services, including but not limited to:

a) health insurers as defined by Section 38-71-92;

b) employee health plans offered by self-insured employers;

c) group health coverage offered by fraternal organizations, professional associations, or other organizations;

d) state and federal health care programs; and

e) state and local public employees health plans.

7) “Health provider networks” means an organization of health care providers which offers health services to a resident of this State. An organization may be a partnership, corporation including an association, a joint stock company, or any other legal entity recognized by the State.

8) “Health service area” means the proposed primary service area of all facilities or entities involved in the cooperative agreement.

9) “Federal or state antitrust laws” means a federal or state law prohibiting monopolies or agreements in restraint of trade, including the Federal Sherman Act and Clayton Act, the Federal Trade Commission Act, and Chapters 3 and 5 of Title 39 of the 1976 Code.

10) “Party” or ‘Party to a cooperative agreement’ means a person who negotiates or enters into a cooperative agreement.

11) “Person” means an individual, a trust or estate, a partnership, a corporation, an association, a joint stock company, an insurance company, a health maintenance organization, a state, a political subdivision of a state, an instrumentality including a municipal corporation of a state, or any legal entity recognized by the State.

12) “A complete application” means a Questionnaire [page 15 of these Regulations] with all applicable questions answered, and a narrative addressing each point set out in Section 202, and any additional information requested by the Department pursuant to Section 302.

13) “Receipt” means actual receipt of a written document.

SECTION 103. Applicability:

This regulation applies to health care providers, health care networks, and health care purchasers who apply for a Certificate of Public Advantage and to those who receive a Certificate of Public Advantage.

The issuance of a Certificate of Public Advantage is not required in order for health care providers, purchasers or networks, to negotiate and enter into cooperative agreements with other health care providers. Parties to a cooperative agreement may apply to the Department for a Certificate of Public Advantage, should they desire.

CHAPTER 2 APPLICATION

SECTION 201. Application Submission:

Two copies of the application shall be forwarded to the Department in the format described in Section 202. The application shall be on 8 ½ × 11 paper, one side only, and three hole punched on the left side.

SECTION 202. Application:

In answering the following questions, the applicants may refer to specific sections of the executed cooperative agreement in lieu of repeating the required information.

For each response for which confidentiality has been sought pursuant to Section 310, include the following statement: "Submitted separately under claim of confidentiality."

An application shall consist of:

- (a) PART A. Questionnaire.

**QUESTIONNAIRE
PART A.**

Parties To The Cooperative Agreement

Name	Title	Address
1.		
2.		
3.		
4.		
5.		

Brief Description of Proposal

Describe Proposed Market Area

Person Responsible For This Application Title

Address Telephone Number

All parties hereby certify that the information contained in this Application, including all assurances and attachments, are accurate and correct to the best of our knowledge and belief.

Signature _____ Date _____

- (b) PART B. Narrative

1.(A) Describe the agreement in detail, including all the parties and each party's responsibilities, obligations and commitments.

(B) State whether the project will change the existing services of a health care provider.

(C) Describe any shared services.

(D) Describe any obligation for future commitments or negotiations.

(E) Describe the nature and scope of the cooperation that is required by each party to the agreement.

(F) Describe in detail any monetary or other consideration passing to a party under the cooperative agreement.

(G) Describe in detail any merger, lease, change of ownership or other change in control of the assets of any party to the cooperative agreement.

2. Provide the total cost of the project and the costs to be incurred by category. Examples include but are not limited to consultants, capital costs, and management costs. Describe what part of the cost is borne by each party.

3. Provide the following ownership disclosure for each party in the agreement.

(A) The name of the party;

(B) Address of each party;

(C) The complete title of the governing body (if any);

(D) The name, title and address of the presiding officer of the governing body;

(E) The name and mailing address of all persons and/or entities having 5% or more ownership interest or owner's equity of any of the parties to include a schedule of percent and type ownership of each;

(F) A list of all officers of each party;

(G) A copy of any agreement, contract, option, understanding, intent or other arrangement that will effect a change in any of the information provided in subparagraphs (A) through (F) above. If such an agreement exists, provide similar information for the party after the terms of the arrangement are carried out; and

(H) If any of the licensees of the cooperative agreement are a subsidiary corporation, provide a diagram of the licensee's relationship to the parent corporation and list the name and address of the parent corporation.

4. Demonstrate and document that the likely benefits accruing from the cooperative agreement outweigh the likely disadvantages. At a minimum, include the economic, administrative, and patient impact of the agreement. Describe how the cooperative agreement will foster cost containment, eliminate duplicate

services or otherwise positively impact the health care system. Describe how the cooperative agreement will reduce competition, reduce patient choice, or otherwise negatively impact the health care system.

5. Discuss alternatives that have been considered and the advantage and disadvantages of each alternative.

6. Discuss any improvements in access and any problems patients may experience, such as costs, availability, or accessibility, upon initiation of the proposed cooperative agreement.

7. Identify any costs associated with implementation of the cooperative agreement and provide documentation of the availability of the necessary funds.

8. Describe the current service area of each party to the cooperative agreement and describe the proposed service area upon initiation of the cooperative agreement.

9. Describe the current market share of each party to the cooperative agreement and describe the proposed market share upon initiation of the cooperative agreement.

10. Provide a current annual budget for each party involved in the cooperative agreement and a three year projected budget for all entities after the initiation of the cooperative agreement. The budgets must be in sufficient detail so as to determine the fiscal impact of this cooperative agreement on each party. The budgets must be prepared by a Certified Public Accountant (CPA) and all assumptions used must be shown.

11. Document that the proposed agreement is economically feasible both immediately and long term. Describe the impact that the cooperative agreement will have on costs per unit of service.

12. Describe how the agreement enhances or restricts health care services to Medicaid, indigent or charity patients.

13. Provide the name, address and telephone number of the individual who should be contacted for monitoring the implementation of this agreement.

14. Provide a timetable for implementing all components of the cooperative agreement.

15. Provide any additional information that would assist the Department in evaluating this cooperative agreement.

(c) Part C. Programmatic Documents

1. An executed copy of the negotiated cooperative agreement between all parties; or

2. A written copy of the negotiated cooperative agreement and documentation that the proposed subject has been approved by the governing body of each party.

(d) Part D. Assurances

The parties must furnish written assurance of each of the following:

1. that the parties will submit to the Department for approval any changes that occur to the approved cooperative agreement;

2. that the parties will carry out the agreement in accordance with the approved application;
3. that the parties understand that the Department may revoke a Certificate of Public Advantage at any time for reasons outlined in Section 503 of these regulations;
4. that the Department or its authorized representatives at any time during normal hours of operation shall be allowed to make an on-site inspection to determine compliance in accordance with the application for which the Certificate of Public Advantage was issued;
5. that the parties will cooperate with the Department or any investigation regarding compliance with the application for which the Certificate of Public Advantage was issued by providing relevant information in a timely manner, assisting in the collection of data, or satisfying other relevant requests from the Department;
6. that the parties will submit at least every two years, the information required by Section 502 of these regulations;
7. that this cooperative agreement does not involve price fixing, predatory pricing or illegal tying arrangements;
8. that the parties understand that the issuance of a Certificate of Public Advantage does not exempt any of the parties from compliance with the provisions of *Regulation 61-15, Certification of Need for Health Facilities and Services*.

CHAPTER 3 DISPOSITION OF APPLICATION

SECTION 301. Submission of Application:

Two copies of the application, and the filing fee set forth in Section 509 shall be submitted to the Bureau of Health Facilities and Services Development, S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC 29201.

SECTION 302. Additional Information:

(A) After receipt of an application and the appropriate filing fee, the Department will review the application. The Department may request additional information within thirty days of receipt of the application. The applicant will have thirty days from the date of the request to submit the additional information.

(B) If the additional information submitted in response to the Department's request is incomplete, the Department will have fifteen (15) days in which to request further information. If information necessary to deem the application complete is not submitted within thirty (30) days of the second request, the application will be considered withdrawn. An application that is withdrawn does not preclude the applicant from resubmitting a new application.

(C) An application is complete when the Department notifies the applicant that all necessary information has been received or when no request for additional information has been made within thirty days of receipt of the original application.

SECTION 303. Notice and Opportunity for Public Hearing:

(A) Upon receipt of an application and the appropriate filing fee the Department shall publish in the State Register a notice of the receipt of the application.

(B) An affected person as defined in these regulations who requests a public hearing must do so in writing within thirty days of notice pursuant to Section 304 that a completed application has been received by the Department.

(C) The Department will determine whether a public hearing will be held; grounds for denying a public hearing include, but are not limited to, a finding that the requestor is not an affected person. When such a public hearing is held, thirty days prior notice of the hearing will be provided to affected persons. The written notification of the hearing shall include the proposed schedule for review, time, date and place of the public hearing. The public hearing shall provide an opportunity for any person to present information relevant to the application.

SECTION 304. Notification of Affected Persons:

Upon the Department's determination that an application is complete, the Department shall publish in a newspaper having general circulation in the area a public notice that the cooperative agreement application is complete, and when affected persons may request a public hearing. The public notice shall run three consecutive days. Any affected person who has requested in writing to be notified of the determination of the completeness of an application shall be notified in writing by the Department.

SECTION 305. Review by the S.C. Attorney General:

Upon receipt of a completed application, the Department shall forward a copy of the application to the S. C. Attorney General. After review in accordance with SC Code § 44-7-550, the Attorney General may advise the Department in writing to approve or deny the application. If no report is received from the Attorney General within thirty days, the Department will consider that as a recommendation to approve the request. If the Attorney General recommends denial of the Certificate of Public Advantage, the Department will consider the reasons therefor. The Attorney General's opinion is advisory and DHEC is responsible for rendering the final decision.

SECTION 306. Review Time Frames:

The Department must make a decision on the complete application within 60 days of the receipt of a complete application or notification to the applicant that an application is complete, if additional information has been requested, or within sixty days of any public hearing, whichever is later.

SECTION 307. Department Decision:

On the basis of staff review of the record established by the Department, including but not limited to comments from the Attorney General's office, the application, written and verbal comments by affected persons and other persons concerning the application, data studies, literature and other information available to the Department, the staff of the Department shall make a proposed decision to grant or deny the Certificate of Public Advantage. The proposed decision of the Department shall be in writing and shall set forth the basis for the decision. The Department shall furnish a copy of the decision to applicants and any affected persons who have asked to be notified. The proposed decision becomes the final agency decision within fifteen (15) days after the receipt of a notice of the proposed decision by the applicant or an affected person who has requested to be notified of the decision, unless a contested case hearing is requested

pursuant to *Chapter 5-Appeals* of this regulation. The Department's proposed decision is not final until the completion of the contested case proceedings. The Department shall publish its final decisions in the State Register.

SECTION 308. Project Changes During Review Period:

The Department will review any amendments submitted during the review process and may notify the applicant that the amendments constitute a new application, and that the requirements of Section 301, 302, and 303 of this regulation must be complied with. All applicable times shall be counted as though the amendment were a new application.

SECTION 309. Validity of Certificate of Public Advantage:

The Certificate of Public Advantage, if issued, is only valid for the project described in the application including parties involved, services to be offered, mergers or consolidations approved, or other factors as set forth in the application, except as it may be modified in accordance with these regulations. Implementation of a project or undertaking a project that is not in accordance with the Certificate of Public Advantage application or conditions subsequently agreed to by the applicant and the Department may be grounds for revocation of the Certificate of Public Advantage.

SECTION 310. Proprietary Information:

Information obtained by the Department from the parties requesting a Certificate of Public Advantage shall be available to the public in accordance with the Freedom of Information Act unless the Department determines that the information is protected from disclosure. The Department will make this determination if an applicant submits the information sought to be protected separately, clearly marked as "Confidential", and submits justification that the information is entitled to protection from disclosure under one or more of the grounds therefore in the Freedom of Information Act. Such grounds include but are not limited to:

- 1) Trade secrets including feasibility planning, marketing studies, and evaluations and other materials which contain references to potential customers, competitive information, or evaluations;
- 2) Information of a personal nature where the public disclosure thereof would constitute unreasonable invasion of personal privacy;
- 3) Documents of and documents incidental to proposed contractual arrangements and documents of and documents incidental to proposed sales or purchases of property; or
- 4) Correspondence or work products or any other material that would violate attorney-client relationships.

SECTION 311. Administrative and Judicial Review:

Upon receipt of the advice of the Attorney General or at the end of the review period outlined in Section 306 of these regulations, the Department shall issue a staff decision approving or denying the application for a Certificate of Public Advantage. The Department's staff decision is final fifteen days after receipt by the applicant unless an administrative appeal is commenced in accordance with applicable regulations. The applicant or affected party is entitled to administrative and judicial review in accordance with the State's Administrative Procedures Act.

SECTION 312. Conditional Approval

The Department may establish conditions for approval that are reasonably necessary to ensure that the cooperative agreement and the activities engaged under it are consistent with these regulations and its purpose to promote cooperation and limit health care costs; protect against abuse of private economic power; improve access to care; improve efficiencies in the delivery of care, including improving economics of scale in the delivery of services; reduce or eliminate unnecessary duplication of services or technology; and to ensure that the activity is appropriately supervised and regulated. Such conditions shall be stated in the Certificate of Public Advantage and shall be fully enforceable.

CHAPTER 4 CRITERIA FOR REVIEW

SECTION 401. Issuance of a Certificate of Public Advantage:

The Department shall issue a Certificate of Public Advantage for a cooperative agreement if it determines that the applicant has demonstrated that the likely benefits resulting from the agreement outweigh the likely disadvantages from the agreement; and the reduction in competition likely to result from the agreement is reasonably necessary to obtain the benefits likely to result.

SECTION 402. Evaluation of Benefits and Disadvantages:

1. In evaluating the benefits likely to result from the cooperative agreement the Department shall consider, but is not limited to:

- a) enhancement of the quality of health and health related care provided to South Carolina citizens;
- b) preservation of health care providers close to communities traditionally served by those providers;
- c) gains in the cost-efficiency of the services offered by health care providers or purchasers involved;
- d) improvements in the use of health care provider resources and equipment;
- e) avoidance or elimination or reduction of duplication of health care resources;
- f) improvements in access to health care for citizens in the community;
- g) support of the agreement by purchasers and payers in the health service area;
- h) the extent of financial risk-sharing by the parties as a result of the agreement;
- i) the provision or enhancement of health care services to Medicaid, indigent, or charity care patients by the parties to the agreement.

2. In evaluating the disadvantages likely to result from the agreement, the Department shall consider but is not limited to:

- a) the likely adverse impact, if any, on the ability of the health care purchasers to negotiate optimal payment and service arrangements with the health care providers or health provider networks;

b) the extent of any reduction in competition among health care providers, purchasers, or other persons furnishing goods or services to or in competition with health care providers or purchasers that is likely to result directly or indirectly from the health care cooperative agreement;

c) the likely adverse impact, if any, on patients in the quality, availability, and price of health care services;

d) the extent to which the agreement may increase the costs of prices of health care at a hospital or other health care provider which is a party to the agreement;

e) the extent to which services to Medicaid, indigent, or charity care patients are adversely impacted by the agreement.

SECTION 403. Evaluation of Impact of Reduction of Competition:

In evaluating whether the reduction in competition is necessary to obtain the likely benefits, the Department shall consider, but is not limited to:

1) The availability of arrangements that:

a) are less restrictive to competition and achieve the same benefits;

b) offer a more favorable balance of benefits over disadvantages attributable to a reduction in competition likely to result from the agreement;

2) The ease with which health care providers or health care purchasers may obtain contracts with other health plans;

3) The difficulty in establishing new competing health plans in the relevant geographic market, including the ability to offer services requiring a certificate of need or purchasing these services from another health care provider or health provider network; and

4) The sufficiency of the number or type of providers under contract with the health plan available to meet the needs of plan enrollees.

SECTION 404. Additional Considerations:

The Department may consider other information or factors relevant to the purposes of the Health Care Cooperation Act and this regulation. The information or factors so considered shall be specifically stated in the staff decision. Should the Department consider other information or factors that are not published in these regulations, the Department will notify the applicant as soon as is reasonable practical and will provide them an opportunity to respond.

CHAPTER 5 MONITORING

SECTION 501. Monitoring:

The Department shall actively monitor and regulate agreements approved under this regulation. The Department may request information, conduct inspections, or conduct audits whenever necessary to ensure that the agreements remain in compliance with the conditions of approval and the approved application. The same rules apply to information acquired by the Department through information received, inspections

conducted or audits conducted as in Section 310 of these regulations. The Department shall provide the applicant at least ten day notice of a compliance audit. The Department shall afford the applicant at least ten days to respond to any complaint, question or problem identified by the Department.

SECTION 502. Activities Report:

(A) During the time the Certificate of Public Advantage is in effect, a report on the activities pursuant to the cooperative agreement must be filed by the parties to the cooperative agreement with the Department at least every two years. Based on this report the Department shall determine whether the cooperative agreement continues to comply with the terms of the Certificate of Public Advantage.

(B) The report shall contain, but not be limited to the following:

1. a detailed description of the implementation of the approved application, contract or other agreement between parties;
2. a detailed description of any changes, modifications, deviations, amendments, or other differences from the approved application;
3. an assessment of the success or failure of the agreement to accomplish the goals, benefits, or other results expected from the approved application. Provide any supporting documentation on which these conclusions are based; and
4. any additional information the parties feel will assist the Department in order to make the assessment required in this Section.

SECTION 503. Revocation of Certificate of Public Advantage:

The Department may revoke a certificate upon a finding that:

(A) the parties to the agreement are not complying with its terms or the conditions of approval as stated in the Certificate of Public Advantage, or the agreement is not in substantial compliance with the terms of the application or conditions of approval; or

(B) the likely benefits resulting from the certified agreement no longer outweigh any disadvantages attributable to any potential reduction in competition resulting from the agreement; or

(C) the Department's certification was obtained as a result of intentional material misrepresentation to the Department or as the result of coercion, threats, or intimidation toward any party to the cooperative agreement; or

(D) failure to pay the annual monitoring fee.

SECTION 504. Administrative and Judicial Review:

A decision by the department to revoke a Certificate of Public Advantage is subject to administrative and judicial review in accordance with the State's Administrative Procedures Act.

SECTION 505. Civil or Criminal Enforcement:

Nothing in this regulation limits the authority of the Attorney General to initiate civil enforcement action or criminal prosecution upon the determination that health care providers, health providers networks, or health care purchasers have exceeded the scope of the Certificate of Public Advantage approved by the Department.

SECTION 506. Termination of Agreements:

A party to a cooperative agreement who terminates the agreement shall notify the Department within fifteen days of the termination. If all parties terminate their participation in the cooperative agreement, the Department shall revoke the Certificate of Public Advantage for the agreement.

SECTION 507. Certificate of Need Requirement:

Nothing in this Regulation exempts health care providers or purchasers from compliance with the provisions of the S. C. Certification of Need Program.

SECTION 508. Changes After Receipt of a Certificate of Public Advantage:

If an applicant amends, alters, or otherwise changes the agreement after receipt of a Certificate of Public Advantage, the Department will decide whether or not the amendment is substantial and thereby requires another review. A change in the application will be considered substantial if the Department believes that the change materially changes the reasons for approval, might materially impact the benefits or disadvantages to the community to be served, or will change the service area of the original application. The addition or deletion of a party to the agreement does not necessarily constitute a substantial change unless the Department believes that the above mentioned criteria will occur.

SECTION 509. Fees:

(A) Filing Fee: A non-refundable filing fee shall accompany each application for a Certificate of Public Advantage. The filing fee shall be \$3,000 per party to the cooperative agreement up to a maximum of \$15,000 per application. The filing fee must be received with the application in order for the Department to accept the application and begin processing the application.

(B) Monitoring Fee: An annual monitoring fee shall be assessed to each approved application for which a Certificate of Public Advantage is in effect. The annual monitoring fee shall be \$5,000 for each Certificate which has five or fewer parties and \$7,000 for each Certificate that involves more than five parties. Failure to pay this fee will result in revocation of the Certificate of Public Advantage.